

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

THIS DOCUMENT RELATES TO:
All Tennessee Actions Against The
St. Thomas Entities

MDL No. 2419
Master Docket No.: 1:13-md-2419-RWZ

Honorable Rya W. Zobel

DEMAND FOR JURY TRIAL

**MEMORANDUM IN SUPPORT OF PSC'S MOTION TO COMPEL THE ST. THOMAS
ENTITIES TO RESPOND TO CERTAIN DOCUMENT REQUESTS**

The Plaintiffs' Steering Committee (the "PSC") moves this Honorable Court, pursuant to Fed. Rule Civ. Pro. 37 and Local Rule 37.1, for an order compelling the St. Thomas Entities¹ to respond to certain interrogatories. After receiving responses to the PSC's initial common discovery requests from the St. Thomas Entities and conducting two separate conferences with the St. Thomas Entities to narrow any dispute over their responses, the PSC now seeks the Court's intervention concerning those issues still in dispute. As grounds for this motion, the PSC respectfully states as follows:

I. Local Rule 37.1 Discovery Conference

The PSC originally served its initial common discovery requests on the St. Thomas Entities on October 9, 2013.² The St. Thomas Entities provided initial responses on December 11, 2013.³ The PSC sent an initial discovery deficiency letter on April 17, 2014 identifying certain deficiencies in the St. Thomas Entities' December 11, 2013 discovery

¹ The Defendants Saint Thomas West Hospital, formerly known as St. Thomas Hospital ("St. Thomas Hospital"), St. Thomas Health ("St. Thomas Health"), and St. Thomas Network ("St. Thomas Network") are collectively referred to as the "St. Thomas Entities".

² See Declaration of Benjamin A. Gastel filed contemporaneously herewith at ¶ 2 (hereinafter the "Gastel Decl.").

³ *Id.* at ¶ 2 and Exs. 1-3

responses.⁴

The parties held a telephonic meet and confer on these issues on May 5 and 6, 2014 where Benjamin Gastel appeared on behalf of the PSC and Yvonne Puig and Marcy Greer appeared, amongst other counsel, on behalf of the St. Thomas Entities. The parties held another telephonic meet and confer on August 4, 2014 attended by Benjamin A. Gastel on behalf of the PSC, and Yvonne Puig and Marcy Greer, amongst other counsel, attended for the St. Thomas Entities.

During these meet and confer sessions, the parties were able to reach agreement on certain items, and the St. Thomas Entities agreed to supplement their initial responses upon the Court entering a common discovery order, which the Court did on September 18, 2014.⁵ Thereafter, the St. Thomas Entities supplemented their discovery responses on November 10, 2014.⁶

The PSC thereafter filed a motion to compel related to certain interrogatories that remained deficient.⁷ Following the filing of this motion to compel the parties engaged in additional meet and confers with Benjamin Gastel appearing on behalf of the PSC along with Adam Schramek and other counsel appearing for the Saint Thomas Entities.⁸ These meet and confer conferences lead to the PSC and the Saint Thomas Entities reaching an agreement as to the original motion to compel after the Saint Thomas Entities agreed to supplement their initial interrogatory responses.⁹ Although the issues related to the Saint Thomas Entities' interrogatory responses were largely resolved, two issues remained:

⁴ *Id.* at ¶ 2 and Ex. 4.

⁵ *See* Dkt. No. 1425.

⁶ Gastel Decl. ¶ 3.

⁷ Dkt. Nos 1549 and 1550..

⁸ Gastel Decl. ¶ 3.

⁹ Dkt. No. 1636.

whether the Saint Thomas Entities would be required to produce the entire Saint Thomas Hospital formulary or simply the portion of it that relates to MPA.¹⁰ In their responses to the PSC's initial common discovery, the St. Thomas Entities have taken the position that a substantive response to certain interrogatories is not necessary due to relevancy or breadth. They have reiterated this position during the two telephonic conferences concerning deficiencies in their discovery responses. The PSC maintains that these objections are without merit and moves the Court to compel the St. Thomas Entities to provide substantive responses to the disputed interrogatories.

II. Factual and Procedural Background

As the Court knows, this litigation arises from a widespread outbreak of fungal meningitis affecting victims in at least 20 states caused by contaminated pharmaceuticals compounded by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC") located in Framingham, Massachusetts.

The defendant, St. Thomas Outpatient Neurosurgical Center ("St. Thomas Clinic"), is a pain clinic located on the St. Thomas Hospital campus in Nashville, Tennessee. Plaintiffs allege that St. Thomas Clinic and its employees and agents knew or should have known of the dangers of using compounded drugs generally, and specifically products compounded by NECC.¹¹ Nevertheless, they decided to purchase injectable steroids from NECC after undertaking zero due diligence.¹² They did nothing to ascertain the safety and quality of NECC's products.¹³ Instead, they decided to purchase the cheapest steroid available.¹⁴ Rather than purchasing purportedly sterile injectable steroids from an under-regulated, out-of-state compounding pharmacy, St.

¹⁰ Gastel Decl. ¶ 3.

¹¹ See Master Complaint, Dkt. No. 545 ¶¶ 152-158, 180.

¹² *Id.* at ¶ 192.

¹³ *Id.*

¹⁴ *Id.*

Thomas Clinic should have purchased medications made by an FDA approved drug manufacturer such as Pfizer.¹⁵

Plaintiffs allege that St. Thomas Clinic is the actual or apparent agent of St. Thomas Hospital, St. Thomas Health and St. Thomas Network. Plaintiffs assert that all of the St. Thomas Entities use a common name, share common officers, share a common location, and are otherwise so inextricably intertwined as to create an agency relationship with St. Thomas Clinic.¹⁶

St. Thomas Clinic is co-owned by St. Thomas Network and defendant, Howell Allen Clinic.¹⁷ St. Thomas Network has zero employees and appears to be an empty shell. It, in turn, is owned by St. Thomas Health, the same entity that owns St. Thomas Hospital.¹⁸ St. Thomas Clinic operates on the 9th floor of the Medical Plaza East on the St. Thomas Hospital campus.¹⁹ In other words, patients who visit St. Thomas Clinic must go to St. Thomas Hospital in order to do so.

When patients entered the St. Thomas Clinic, they were greeted by a receptionist wearing a nametag bearing the name: “Saint Thomas Hospital”. Specifically, below is a copy of the nametag worn by Sherri Dezwaan, the clinic’s receptionist²⁰:

¹⁵ *Id.* at ¶ 180.

¹⁶ The Saint Thomas Entities are not named in the Master Complaint. For allegations related to the Saint Thomas Entities, the PSC will use the complaint filed in *Reed v. Ameridose*, Case No. 1:13-cv-12565-RWZ, Dkt. No. 1 as a representative complaint containing allegations against the St. Thomas Entities. This complaint will hereinafter be referred to as the *Reed* Complaint. The St. Thomas Entities filed an answer to this complaint on October 1, 2014 (*Reed*, Case No. Dkt. 1:13-cv-12565-RWZ No. 42).

¹⁷ Saint Thomas Clinic Answer to Short Form Complaint, Dkt. No 1459-1 at ¶ 261.

¹⁸ Gastel Decl. ¶ 4 and Ex. 5.

¹⁹ Saint Thomas Clinic Answer to Short Form Complaint, Dkt. No 1459-1 at ¶ 275.

²⁰ Gastel Decl. at Ex. 6.



Ms. DeZwaan was a Howell Allen employee who worked at the St. Thomas Clinic while wearing a Saint Thomas Hospital nametag.²¹ The employees and leadership of the St. Thomas Entities, Howell Allen, and St. Thomas Clinic are likewise intertwined.²²

Moreover, the St. Thomas Entities and St. Thomas Clinic hold themselves out to the public as one singular entity, further blurring any distinctions between or among them. The St. Thomas Entities and St. Thomas Clinic share the St. Thomas name and the same location on the St. Thomas Hospital campus. They intentionally foster the public perception that they are one united entity through a large scale marketing campaign highlighting the tag line: “*St. Thomas Health: One Name, One Healing Community.*” An example of that marketing campaign is as follows:

²¹ *Id.*

²² See Reed Complaint ¶¶ 275-277.



Presenting a united face to the public, the St. Thomas Entities – as one, or at least as an indistinguishable tangle – Plaintiffs allege creates an actual or apparent agency relationship with St. Thomas Clinic.²³

The Plaintiffs allege that the St. Thomas Entities permitted their agent to procure injectable steroids from NECC without conducting basic due diligence and without using patient-specific prescriptions and injected those steroids into patients.²⁴

Based upon the above allegations, and pertinent to the pending motion, Plaintiffs assert, amongst others, claims for agency, apparent agency, and *respondeat superior*.²⁵ Additionally, Plaintiffs’ substantive claims against the St. Thomas Clinic allege that the St. Thomas Clinic failed to follow the American Society of Health-System Pharmacists’ guidelines, which establish due diligence standards healthcare providers should follow when purchasing compounded pharmaceuticals.²⁶ The Saint Thomas Clinic appears to defend these allegations,

²³ Reed Complaint ¶¶ 274-286.

²⁴ *Id.* ¶ 281.

²⁵ *Id.* at ¶¶ 274-286.

²⁶ Reed Complaint ¶ 120; *see also* Master Complaint, Dkt. No. 545 ¶¶ 152-158, 180, 192.

in part, on the claim that they satisfied the standard of care in the procurement of compounded pharmaceuticals and well-known industry regulations do not create a duty upon the Saint Thomas Clinic to satisfy those regulations (principally because Saint Thomas Clinic admits that it did not follow ASHP guidelines).²⁷

III. LEGAL STANDARD

“Parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party’s claim or defense.”²⁸ Relevance is broadly construed to encompass “any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case.”²⁹ This very court has previously noted that “[t]he scope of discovery is very broad, and information is discoverable if there is any possibility it might be relevant to the subject matter of the action.”³⁰ “Relevant information includes any matter that is or may become an issue in the litigation.”³¹ Because Rule 26(b) sets a “very low threshold for relevancy,” courts should “err in favor of discovery rather than against it.”³²

IV. The PSC’s Position as to Each Contested Document

²⁷ Saint Thomas Clinic Answer to Master Complaint, Dkt. No. 1455, ¶¶ 46, 54, 152-158; Saint Thomas Clinic Answer to Short Form Complaint, Dkt. No. 1459-1 at ¶ 120. *see also* Tenn. Code Ann. § § 29-26-115; *Mabon v. Jackson-Madison County Gen. Hosp.*, 968 S.W.2d 826 (Tenn. Ct. App. 1997) (holding that Plaintiff’s tendered expert must be familiar with the standard of care in the community in which the defendant practices or a similar community, and without such threshold evidence of the locality’s standard of practice, plaintiff cannot demonstrate a breach of duty.).

²⁸ Fed. R. Civ. P 26(b)(1).

²⁹ *Oppenheimer Fund v. Sanders* 437 U.S. 340, 351 (1978); *Ameristar Jet Charter, Inc. v. Signal Composites, Inc.*, 244 F.3d 189, 192 (1st Cir. 2001) (“The Supreme Court has long recognized that the Federal Rules of Civil Procedure are to be construed liberally in favor of discovery.”)

³⁰ *Gulbankian v. MW Mfrs., Inc.*, Case No. 10-10392-RWZ, 2013 U.S. Dist. LEXIS 69773 (D. Mass. 2013, Judge Zobel) (internal quotations omitted); *see also In re Heparin Prods. Liab. Litig.* 273 F.R.D. 399, 406 (N.D. Ohio 2011) (“If there is any possibility that the information may be relevant to the general subject matter of the action.”) citing *Oppenheimer*, 437 U.S. at 351.

³¹ *Multi-Core, Inc. v. Southern Water Treatment Co.*, 139 F.R.D. 262, 264 n.2 (D. Mass. 1991); *see also Chubb Integrated Systems Limited v. National Bank of Washington*, 103 F.R.D. 52, 59 (D.D.C. 1984) (“The concept of relevancy is broadly construed at the discovery stage of an action, and discovery rules are to be accorded liberal treatment.”).

³² *Kipperman v. Onex Corp.* (N.D. Ga. Apr. 25, 2008) 2008 U.S. Dist. LEXIS 34519, *28.

The PSC seeks an order compelling the St. Thomas Entities to produce its hospital formulary and an index of their policies and procedures. The number of the interrogatory below corresponds to the numbers in the interrogatories posed to St. Thomas Health, unless otherwise indicated.³³ For the Court's convenience, the interrogatories have been grouped into seven broad categories.

1. The entire Saint Thomas Hospital Formulary Should Be Produced.

SAINT THOMAS HEALTH REQUEST FOR PRODUCTION NO. 23: Produce a copy of any emails, reports, memoranda, policies, procedures, guidelines or other material that addresses the purchase, administration and/or use of any medications on the St. Thomas Hospital Campus.

OBJECTION: STHe objects to this request to the extent it seeks information protected from discovery by TENN. CODE ANN. § 29-26-122(d) and/or TENN. CODE ANN. § 63-1-150(d). STHe objects to this request as it seeks information that is irrelevant, beyond the scope of permissible discovery under FED. R. CIV. P. 26, and not reasonably calculated to lead to the discovery of relevant or admissible evidence regarding any allegation in the Complaints. STHe also objects to this request as overly broad and unduly burdensome because it is not appropriately limited in time. STHe also objects to this request as seeking electronically stored information, without appropriately limited time constraints, that is not reasonably accessible due to undue burden or cost, and this burden and expense outweighs any likely benefit of the requested information. STHe does not interpret this request as including STHe legal counsel; nor does it interpret this request as seeking information protected by the attorney-client privilege or work-product doctrine. To the extent Plaintiffs use this request to seek protected information or to impose an unnecessary and unwarranted privilege log burden, STHe objects to those attempts. STHe further objects to the request to the extent it seeks information from entities leasing space on the "St. Thomas Hospital Campus" as that information is not in STHe's possession, custody, or control.

Importantly for the issue at hand, Saint Thomas Hospital's formulary is a list of prescription medication authorized to be used in Saint Thomas Hospital's operations. As

³³ In some instances related to the disputed interrogatories, the PSC propounded identical interrogatories to each of the St. Thomas Entities, and the St. Thomas Entities propounded the same responses to the overlapping interrogatories. For example, Interrogatory No. 12 to St. Thomas Health is the identical interrogatory as Interrogatory No. 17 propounded to Saint Thomas Hospital and those entities had identical objections to that interrogatory. For the Court's convenience, this memo will simply cite one of the disputed interrogatories and identify in a footnote the identical interrogatory number propounded to the other St. Thomas Entities.

part of its supplemental interrogatories, the Saint Thomas Entities did produce the formulary policy and a redacted version of the formulary addressing only the entries related to MPA. This limited production, however, is simply insufficient.³⁴

Plaintiffs' allege that Saint Thomas Hospital failed to adequately supervise its agent's purchase of compounded pharmaceuticals from NECC. Central to this inquiry is: what is Saint Thomas Hospital's customary and approved pharmaceutical purchase regime? The formulary is a document that codifies such a regime and will shed light on Saint Thomas Hospital's understanding of the risks associated with compounded pharmaceuticals. Saint Thomas Hospital in sworn interrogatories described its process of purchasing medications as follows:

INTERROGATORY NO. 11: Explain in detail St. Thomas Hospital's policies and procedures regarding the purchase of medications, including but not limited to a description of any applicable policies and procedures from Ascension.

ANSWER: Subject to and without waiving the foregoing objections, as of 2012, STH generally purchased medications through McKesson, a group purchasing organization, by selecting from among available medications listed by McKesson in an online database. In the event that a medication that STH wanted to purchase was not available from McKesson, STH pharmacists followed the STH Formulary System policy and pharmacy procurement policies, which are being served herewith.

Although Saint Thomas Health produced the formulary policy it did not produce the entire formulary itself (i.e. the actual list of approved medications).

As alleged in the Master Complaint, compounded medications are generally more dangerous than medications manufactured by FDA regulated pharmaceutical companies.³⁵ Plaintiffs' negligence claims are premised upon the assertion that St. Thomas Clinic was negligent and reckless in its decision to switch from steroids made by FDA regulated

³⁴ Gastel Decl. ¶ 4.

³⁵ Master Complaint Dkt. No. 545, ¶¶ 48-55.

pharmaceutical companies to steroids made by NECC.³⁶

The formulary is the one of the key pieces of evidence showing how Saint Thomas Hospital treats compounded pharmaceuticals as it relates to their FDA regulated equivalents.

Further, if it can be shown that the purchase of MPA by the Saint Thomas Clinic was not in accordance with the Saint Thomas Hospital's formulary, that is strong evidence of the Saint Thomas Entities' failure to adequately supervise its agent's purchase of same.

Accordingly, the formulary clearly meets the low threshold of relevancy requiring its production in this case.

2. An Index of All Policies And Procedures Should Be Produced

SAINT THOMAS HEALTH REQUEST NO. 18: Produce a copy of all of Saint Thomas Health's written policies, procedures and guidelines.

OBJECTION: STHe objects to this request as it seeks information that is irrelevant, beyond the scope of permissible discovery under FED. R. CIV. P. 26, and not reasonably calculated to lead to the discovery of relevant or admissible evidence regarding any allegation in the Complaints. STHe also objects to this request as overly broad and unduly burdensome because it is not appropriately limited in time, nor is it limited by subject matter of the policy or procedure.

RESPONSE: Subject to and without waiving the foregoing objections, STHe will produce non-privileged, responsive documents in the possession, custody, or control of this Defendant.

Accepting that the request as phrased may be considered overbroad since at this time the PSC does not know what policies may be implicated by the request, the PSC proposed that the Saint Thomas Entities simply produce a copy of an index of all of its policies and procedures that would help the PSC evaluate which policies may be applicable in this case. The Saint Thomas Entities refused.

³⁶ *Id.* at ¶ 234.

As explained in greater detail above, this case involves, along with direct allegations of negligence against the Saint Thomas Entities, vicarious liability claims. Policies and procedures that provide system-wide definitions and instructions are highly relevant to establishing the facts supporting vicarious liability claims. For instance, the Corporate Responsibility Program (which is a policy meant to “ensure that appropriate ethical and legal business standards and practices are maintained and enforced”) states the following:

Saint Thomas Health...refers to all legal entities that are directly or indirectly controlled by Saint Thomas Health and, and, as applicable, to STHe Organizations controlled by Saint Thomas Health. An entity is controlled by Saint Thomas Health if Saint Thomas Health has (1) the authority, either directly or indirectly, to act as the controlling member, shareholder or partner of the entity, (2) the authority to appoint, elect or approve at least a majority of the individual members, shareholders, or partners of the entity, or (3) the authority to appoint, elect or approve at least a majority of the governing body of the entity.³⁷

Obviously that definition in the context of this policy is highly applicable to Plaintiff’s agency claims against the Saint Thomas Entities. Interesting, the policy goes on to detail Ascension’s detailed role in the Saint Thomas Health corporate responsibility program and establishes that Ascension, Saint Thomas Health’s parent company, plays a significant role in the management and operation of Saint Thomas Health. Other policies may show similar relationships between the Saint Thomas Entities, the Saint Thomas Clinic, and other defendants in this MDL.

Moreover, it is nearly impossible for the PSC to determine what policies and procedures could be applicable to these claims without knowing the universe of such policies and procedures. After all, Saint Thomas Health may have specific policies regarding the purchase of compounded pharmacists or specific policies regarding the management of joint ventures and co-owned facilities like the Saint Thomas Clinic. The PSC at this time simply does not know and an index of policies will go a long way to helping it answer this question. Such indexes are

³⁷ Gastel Decl., Ex. 7.

routinely produced in medical malpractice actions in this state and the Saint Thomas Entities' refusal to do so is simply unsupported.

In short, the PSC should be permitted to investigate the internal workings of the Saint Thomas Entities to determine the roll they plan in managing and controlling their agent the Saint Thomas Clinic.³⁸ Its policies and procedures are key probative evidence of this relationship. Accordingly, an index of policies should be produced to help the PSC determine which policies and procedures are applicable to its potential vicarious liability claims.³⁹

V. Conclusion

For the foregoing reasons, the PSC respectfully requests that the Court compel the Saint Thomas Entities to produce:

- A copy of the Saint Thomas Hospital's approved formulary; and
- An index of all of Saint Thomas Entities' policies and procedures.

January 23, 2015

Respectfully submitted,

s/ J. Gerard Stranch IV

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³⁸ *Id.*

³⁹ Alternatively, the Court could simply require the Saint Thomas Entities to produce all of their policies and procedures as stated in the request.

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, J. Gerard Stranch, IV, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: January 23, 2015

/s/ J. Gerard Stranch, IV

J. Gerard Stranch, IV